



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,876	06/25/2003	Paul Goode	13569.0012US01	3012

45458 7590 03/22/2006

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH/
GUIDANT/CPI
PO BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER

FAULCON JR, LENWOOD

ART UNIT PAPER NUMBER

3762

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/603,876

Applicant(s)

GOODE, PAUL

Examiner

Lenwood Faulcon, Jr.

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,7-15,17-27,29-44 and 46-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,7-15,17-27,29-44 and 46-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed December 20, 2005 have been fully considered but they are not persuasive.
2. Applicant's arguments with respect to claims 1, 3, 5, 7-15, 17-27, 29-44, 46-49 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. Claims 1, 3, 8-14, 17, 19, 29, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (U.S. Patent No. 6,058,328) as applied in the previous Office Action of September 22, 2005 and below, and further in view of Chirife (U.S. Patent No. 5,154,171).

Levine et al. does not specifically teach of the use of ejection fraction as a cardiac parameter. Chirife teaches of a rate adapter pacemaker designed to accommodate changes in a patient's metabolic demand by utilizing ejection fraction as the rate controlling parameter (col. 3 lines 48-57).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Levine et al. with the teachings of Chirife. Levine et al. and Chirife both teach of cardiac stimulating devices that sense cardiac parameters to cardiac conditions, and thus teach of analogous arts. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Levine et al. to include the ejection fraction as a detected cardiac

parameter, as taught by Chirife, since this would enhance the system's ability and accuracy of detecting sudden cardiac death conditions.

4. Claims 5, 7, 24-27, 30-42, 44 and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (U.S. Patent No. 6,058,328), as applied in the previous Office Action of September 22, 2005.

Examiner takes the position that Levine et al. inherently teaches of the ability for detecting the difference between resting and non-resting parameters to predict the onset of a sudden cardiac death episode (col. 29 lines 41-48 and claim 46).

Levine et al. also teaches of detecting the occurrence of a myocardial infarction and other cardiac conditions that affect a heart's blood flow (col. 33 lines 13-21). In regards to claims 30, 32, 46 and 48, Examiner takes the position that although Levine et al. does not specifically teach of monitoring for a drug regimen or congestive heart failure, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Levine et al. to include the detection of various cardiac conditions, since this would enhance the system's ability and accuracy in predicting and treating sudden cardiac death, as suggested by Levine et al. in the teaching of monitoring for various cardiac conditions that inherently may effect blood flow (col. 33 lines 13-21).

5. Claims 15, 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (U.S. Patent No. 6,058,328) in view of Chirife (U.S. Patent No. 5,154,171) as applied to claim 1-3, 8-14, 17, 19, 29, 43 above, and further in view of Causey et al. (U.S. Patent No. 4,809,697).

Levine et al. teaches of an implantable stimulator communicating with external device (col. 11 lines 1-15). Levine et al. further teaches that the external device could be of the type commonly known in the art such as the device as taught by Causey et al. (col. 11 lines 3-5). Causey et al. teaches of external device for communicating with an implantable stimulator, in which the external device comprising an external memory (Figure 1).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Levine et al. and Chirife for the reasons stated above, and it would have been obvious to further combine these teachings with the teachings of Causey et al. for the reasons stated by Levine et al. (col. lines 3-5). Levine et al., Chirife and Causey et al. all teach of stimulation systems with sensing capabilities and thus teach of analogous arts.

6. Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (U.S. Patent No. 6,058,328) in view of Chirife (U.S. Patent No. 5,154,171) as applied to claim 1-3, 8-14, 17, 19, 29, 43 above, and further in view of Koestner et al. (U.S. Patent No. 5,300,093) as applied in the previous Office Action of September 22, 2005.

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Levine et al. and Chirife for the reasons stated above, and to further combine these teachings with the teachings of Koestner et al. Levine et al., Chirife and Koestner et al. all teach of cardiac stimulation devices that measure cardiac impedance and thus teach of analogous arts. It would have been

obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Levine et al. to have electrodes in various configurations, such as those as taught by Koestner et al., since these configurations may enhance the efficiency and accuracy of sensing.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Langer et al. (U.S. Patent No. 4,202,340), Geddes et al. (U.S. Patent No. 5,058,583), Nappholz et al. (U.S. Patent No. 5,113,869), Sackner (U.S. Patent No. 5,178,151), Street et al. (U.S. Patent No. 6,589,188), Meyer (U.S. 2001/0003160), Geeske et al. (EP 0985429 A2), Schaldach ("Automatic Adjustment of Pacing Parameters Based on Intracardiac Impedance Measurements," Pacing and Clinical Electrophysiology, 1990, pgs 1702-1710.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3762

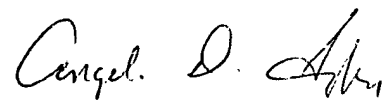
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lenwood Faulcon, Jr. whose telephone number is 571-272-6090. The examiner can normally be reached on Monday-Thursday from 9 to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lenwood Faulcon, Jr.


Angela Sykes

Supervisory Examiner

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3762